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| 09/308,192      | 07/14/99    | BAXTER               | A 229752000600      |

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EXAMINER

LEE, L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1645

8

DATE MAILED:

12/14/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

File Copy

# Office Action Summary

Application No.  
09/308,192

Applicant(s)

Baxter

Examiner

LI Lee

Group Art Unit  
1645



☒ Responsive to communication(s) filed on Sep 25, 1900

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-22 is/are pending in the application

Of the above, claim(s) 5, 6, 11-19, and 22 is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-4, 7-10, 20, and 21 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## DETAILED ACTION

### *Election/Restriction*

1. Applicant's election with traverse of Group I, claims 1-4, 7-10, and 20-21 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that Groups I and II related to the treatment of diseases by immunomodulatory therapy using cell wall components of Mycobacterium and these two groups are a single general inventive concept. This is not found persuasive because the reasons are set forth below.

First, the technical feature linking the inventions of groups I-X does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art because Adam et al (US 4,152,423, May 1, 1979) teach a method of immunomodulatory therapy in a mammal administering a component of the cell wall of Mycobacterium. <sup>comprising</sup> → Not on 892

The Inventions of I and II are drawn to distinct methods which differ in the method objectives (e.g., the treatment of diabetes versus ~~the~~ the treatment of carcinoma, or the treatment of autoimmune disease versus enhancing anti-tumor immune response), method steps, and have different final outcomes.

The requirement is still deemed proper and is therefore made FINAL.

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***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 7-10, and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-4 and 7-10 are indefinite for reciting a improper Markush group for alternative limitations in the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C.", see MPEP 2173.05 (h).

Claims 1-4 and 7-10 are indefinite for reciting the terms "related organism", "analogous components", "chemical equivalents", and "functional equivalents". Those terms are not clearly defined in the specification nor the claims. Without clear definition for the terms, one <sup>of</sup> ordinary skill in the art can not determine the metes and the bounds of the claims.

Claims 3 and 4 are indefinite in the use of abbreviation of IDDM without identification of the meaning of the abbreviation. Amendment of claims to use the full name of abbreviation would obviate this rejection.

Claims 2-4 and 7-10 are indefinite for using the term "A method" in the claims. It is not clear if applicant intends to claim the method according to the preceding claim or to claim a different method according to the preceding claim. The clarification is required.

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Claim 7 is indefinite for the recitation of "any one of claims 1-6" because it is dependent from a non-elected claim 5 or claim 6. The correction is required.

Claim 9 is indefinite for using the term "derived". It is not clearly defined how MAPG or its components are derived from Mycobacterium bovis. Without <sup>a</sup> clearly defined way of derivation, one <sup>of</sup> ordinary skill in the art can<sup>n</sup> not determine the metes and bounds of the claim.

3. Claims 20-21 provide for the use of a cell wall component of Mycobacterium, but, since the claims ~~do~~ not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 20-21 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 10 is directed to a method of immunomodulatory therapy in a human by administering a cell wall component of Mycobacterium to the human. However, the specification does not sufficiently establish that the method can be used as claimed. Applicant's only evidence for immunomodulatory therapy is the mice test and there is insufficient evidence that such studies correlate with efficacy in a human. The mice test is not an art-accepted model for a human. Nor has Applicant set forth any other evidence to establish that a cell wall component of Mycobacterium can be used for immunomodulatory therapy in a human. It is well known in the art that autoimmune diseases in particular, are refractory to anti-autoimmune therapies. These obstacles include the complexity and variation of the pathology of autoimmune diseases in different individuals. The existence of these obstacles establish that the contemporary knowledge in the art would not allow one skilled in the art to use the claimed compositions for anti-autoimmune immunomodulatory therapy in a human without undue experimentation. The art teaches that the ability to treat or inhibiting autoimmune diseases in a human is highly unpredictable and has met with very little success. Applicants have not provided any convincing evidence that their claimed invention is indeed useful as a method for immunomodulatory therapy of autoimmune diseases and have not provided sufficient guidance to allow one skilled in

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the art to practice the claimed invention without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Qin et al (J Immunol. 150 (5), 2072-80, 1993).

Qin et al teach a method of immunomodulatory therapy for the treatment of the autoimmune disease insulin-dependent diabetes mellitus (IDDM) in a mouse comprising administering the components of cell wall of Mycobacterium bovis (Abstract).

8. Claims 1-3 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinson et al (J Clin Lab Immunol. 24 (4), 171-6, 1987).

Robinson et al teach a method of immunomodulatory therapy in a human comprising administering the components of cell wall of Mycobacterium (abstract).

***Status of Claims***

9. No claims are allowed. All claims stand rejected.

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Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee

December 11, 2000

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600